UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): February 23, 2018

KemPharm, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-36913**	**20-5894398**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
2500 Crosspark Road, Suite E126 Coralville, IA		**52241**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (319) 665-2575

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 Regulation FD Disclosure.

On February 23, 2018, KemPharm, Inc., or the Company, issued a press release announcing that the U.S. Food and Drug Administration, or FDA, approved its New Drug Application, or NDA, for Apadaz™ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Apadaz is an immediate release, or IR, combination of the Company's prodrug, benzhydrocodone, and acetaminophen, or APAP. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Also on February 23, 2018, the Company will conduct a conference call and live audio webcast with slide presentation to discuss these matters. A copy of this presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information set forth in this Item 7.01 and contained in the press release furnished as Exhibit 99.1 and the presentation furnished as Exhibit 99.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and is not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01 Other Events.

On February 23, 2018, the Company announced that the FDA approved its NDA for Apadaz for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Apadaz is an IR combination of the Company's prodrug, benzhydrocodone, and APAP. Apadaz was developed from the Company's proprietary LAT™, or Ligand Activated Therapy, platform technology. The Company believes Apadaz is unique among prescription opioids in that it contains a prodrug that is chemically inert, or inactive, on its own. When ingested, enzymes in the gastrointestinal tract cleave the ligand from the prodrug (benzhydrocodone) and release the parent drug (hydrocodone), which can then exert its therapeutic effect. The final approved product labeling for Apadaz includes these and other data points but concludes that the overall results of the clinical program did not demonstrate abuse-deterrence by current measurement standards.

Caution Concerning Forward Looking Statements

This Current Report on Form 8-K and the materials furnished herewith may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can be identified by the use of words such as “may,” “will,” “expect,” “project,” “estimate,” “anticipate,” “plan,” “believe,” “potential,” “should,” “continue” or the negative versions of those words or other comparable words. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements are based on information currently available to the Company and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Risks concerning the Company’s business are described in detail in the Company's Annual Report on Form 10-K for the year ended December 31, 2016, and the Company’s other Periodic and Current Reports filed with the Securities and Exchange Commission. The Company is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release titled “KemPharm Announces FDA Approval of Apadaz™ (benzhydrocodone and acetaminophen) for the Short-Term Management of Acute Pain” dated February 23, 2018.
99.2	Presentation titled "Apadaz™ FDA Approval" dated February 23, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KemPharm, Inc.

Date: February 23, 2018

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, CPA
Chief Financial Officer, Secretary and Treasurer

EXHIBIT 99.1

KemPharm Announces FDA Approval of Apadaz™ (benzhydrocodone and acetaminophen) for the Short-Term Management of Acute Pain

Apadaz is the First Prodrug of Hydrocodone/Acetaminophen to be Approved by FDA

Conference Call and Live Audio Webcast with Slide Presentation Scheduled for Today at 2:30 p.m. ET

Coralville, IA – February 23, 2018 – KemPharm, Inc. (NASDAQ:KMPH), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, announced today that the U.S. Food and Drug Administration (FDA) approved its New Drug Application (NDA) for Apadaz™ for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Apadaz is an immediate release (IR) combination of KemPharm's prodrug, benzhydrocodone, and acetaminophen (APAP).

"The approval of Apadaz is a significant milestone for KemPharm as it creates the opportunity to introduce what we believe is a differentiated product for the short-term management of acute pain," said Travis Mickle, Ph.D., KemPharm President and Chief Executive Officer. "Based on its unique properties, we firmly believe there is a commercial pathway for Apadaz in what is a very high-volume market. We are excited by the opportunity Apadaz offers to patients and for physicians who now have the option of prescribing a differentiated product."

"In addition to today's approval, the U.S. Drug Enforcement Administration (DEA) has indicated that it is their intent to schedule Apadaz as a C-II product and will provide an allocation of the Active Pharmaceutical Ingredient (API) consistent with those scheduling provisions," added Dr. Mickle. "This prompt decision by the DEA essentially completes the regulatory process with both Agencies and allows us to shift our focus towards the product launch."

"Finally, today is a validation of KemPharm's groundbreaking LAT™ (Ligand Activated Therapy) platform and our technological approach to drug development," Dr. Mickle closed. "KemPharm is first and foremost a prodrug development company. The Apadaz approval highlights the value potential that LAT™ offers in the discovery and development of proprietary prodrugs that are designed to be differentiated versions of widely prescribed, currently approved drugs, and that can successfully complete the rigorous regulatory process."

Conference Call Information:

The company will host a conference call and live audio webcast with slide presentation on Friday, February 23, 2018, at 2:30 p.m. ET, to discuss the Apadaz approval by the FDA. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 9788408

The live webcast with accompanying slides will be accessible via the Investor Relations section of the KemPharm website http://investors.kempharm.com/. An archive of the webcast and presentation will remain available following the call.

APADAZ™

Apadaz was developed from KemPharm's proprietary LAT™ (Ligand Activated Therapy) platform technology and is intended for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. KemPharm believes Apadaz is unique among prescription opioids in that it contains a prodrug that is chemically inert, or inactive, on its own. When ingested, enzymes in the gastrointestinal tract cleave the ligand from the prodrug (benzhydrocodone) and release the parent drug (hydrocodone), which can then exert its therapeutic effect. The final approved product labeling for Apadaz includes these and other data points but concludes that the overall results of the clinical program did not demonstrate abuse-deterrence by current measurement standards.

The approval of Apadaz via the 505(b)(2) pathway was based in part on pharmacokinetic studies with Vicoprofen®, Ultracet®, and Norco® in which Apadaz demonstrated exposure to hydrocodone and acetaminophen (APAP) that is expected to result in therapeutic effects equivalent to currently approved immediate-release hydrocodone/APAP combination products when administered orally as intended.

Indication:
Apadaz contains an opioid agonist and acetaminophen and is indicated for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use:
Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Apadaz for use in patients for whom alternative treatment options [e.g., non-opioid analgesics] have not been or are not expected tolerated, or have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Important Safety Information:

Apadaz is contraindicated in patients with: significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment; known or suspected gastrointestinal obstruction, including paralytic ileus; and hypersensitivity to hydrocodone or acetaminophen.

Apadaz contains benzhydrocodone, a Schedule II controlled substance. Apadaz can be abused and is subject to misuse, addiction, and criminal diversion.

Potential risks associated with Apadaz include addiction, abuse, and misuse, life-threatening respiratory depression, neonatal opioid withdrawal syndrome, risks of concomitant use or discontinuation of cytochrome P450 CYP3A4 inhibitors and inducers, acetaminophen hepatoxicity risks from concomitant use with benzodiazepines or other CNS depressants, risk of life-threatening respiratory depression in patients with chronic pulmonary disease or in elderly, cachectic, or debilitated patients, adrenal insufficiency, severe hypotension, serious skin reactions, risks of use in patients with increased intracranial pressure, brain tumors, head injury, or impaired consciousness, hypersensitivity/anaphylaxis, risks of use in patients with gastrointestinal conditions, risk of use in patients with seizure disorders, and withdrawal, risks of driving and operating machinery.

Potential drug interactions with Apadaz include:

- Serotonergic Drugs: Concomitant use may result in serotonin syndrome. Discontinue Apadaz if serotonin syndrome is suspected.
- Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with Apadaz because they may reduce analgesic effect of APADAZ or precipitate withdrawal symptoms.
- Monoamine Oxidase Inhibitors (MAOIs): Can potentiate the effects of hydrocodone. Avoid concomitant use in patients receiving MAOIs or within 14 days of stopping treatment with an MAOI.

Most common adverse reactions (>5%) are nausea, somnolence, vomiting, constipation, pruritus, dizziness, and headache.

The Full Prescribing Information for Apadaz contains the following Boxed Warning:

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; CYTOCHROME P450 3A4 INTERACTION; HEPATOTOXICITY; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse:

Apadaz exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing Apadaz and monitor all patients regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression:

Serious, life-threatening, or fatal respiratory depression may occur with use of Apadaz. Monitor for respiratory depression, especially during initiation of Apadaz or following a dose increase.

Accidental Ingestion:

Accidental ingestion of even one dose of Apadaz, especially by children, can result in a fatal overdose of hydrocodone.

Neonatal Opioid Withdrawal Syndrome:

Prolonged use of Apadaz during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Cytochrome P450 3A4 Interaction:

The concomitant use of Apadaz with all cytochrome P450 3A4 inhibitors may result in an increase in hydrocodone plasma concentrations, which could increase or prolong adverse reactions and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in hydrocodone plasma concentration. Monitor patients receiving Apadaz and any CYP3A4 inhibitor or inducer.

Hepatotoxicity:

Apadaz contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product.

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants:

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of Apadaz and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

For Important Safety Information including full prescribing information, visit: www.kempharm.com

About KemPharm:

KemPharm is a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through its proprietary LAT™ (Ligand Activated Therapy) platform technology. KemPharm utilizes its proprietary LAT™ platform technology to generate improved prodrug versions of FDA-approved drugs in the high need areas of ADHD, pain and other central nervous system disorders. KemPharm's co-lead clinical development candidates are KP415 and KP484, both based on a prodrug of methylphenidate, but with differing extended-release/effect profiles for the treatment of ADHD. In addition, the company has received FDA approval for Apadaz™, an immediate-release combination product candidate of benzhydrocodone, a prodrug of hydrocodone, and acetaminophen. The company is also advancing KP201/IR, an acetaminophen-free immediate-release formulation of the company's benzhydrocodone prodrug candidate. Both Apadaz™ and KP201/IR are intended for the treatment of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. For more information on KemPharm and its pipeline of prodrug product candidates visit www.kempharm.com.

Caution Concerning Forward Looking Statements:

This press release may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue" or the negative versions of those words or other comparable words. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements are based on information currently available to KemPharm and its current plans or expectations and are subject to a number of uncertainties and risks that could significantly affect current plans. Risks concerning KemPharm's business are described in detail in KemPharm's Annual Report on Form 10-K for the year ended December 31, 2016, and KemPharm's other Periodic and Current Reports filed with the Securities and Exchange Commission. KemPharm is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

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Investor Contacts:
Jason Rando / Joshua Drumm, Ph.D.
Tiberend Strategic Advisors, Inc.
212-375-2665 / 2664
jrando@tiberend.com
jdrumm@tiberend.com

Media Contact:
Daniel L. Cohen
Executive VP, Government and Public Relations
KemPharm, Inc.
202-329-1825
dcohen@kempharm.com

Exhibit 99.2

Cautionary Note Regarding Presentation Information

This presentation may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue" or the negative versions of those words or other comparable words. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements are based on information currently available to KemPharm and its current plans or expectations and are subject to a number of uncertainties and risks that could significantly affect current plans. Risks concerning KemPharm's business are described in detail in KemPharm's Annual Report on Form 10-K for the year ended December 31, 2016, and KemPharm's other Periodic and Current Reports filed with the Securities and Exchange Commission. KemPharm is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

Apadaz™ Update – Conference Call Participants

- **Travis Mickle, Ph.D.** – President & Chief Executive Officer
- **Rusty Johnson, M.B.A.** – Chief Business Officer
- **Dan Cohen, M.A.L.S.** – EVP, Government & Public Relations

Apadaz™ Approval

✓ **Announced FDA Approval of Apadaz (benzhydrocodone and acetaminophen) for the Short-Term Management of Acute Pain**

- First prodrug of hydrocodone/acetaminophen to be approved by FDA
- Immediate release (IR) combination of KemPharm's prodrug of hydrocodone, benzhydrocodone, and acetaminophen (APAP)
- Completed DEA product scheduling and quota allocation for Apadaz

✓ **Apadaz Approval is Significant Milestone for KemPharm**

- Opportunity to introduce differentiated product for the short-term management of acute pain
- Demonstrates value potential of KemPharm's LAT™ platform and technological approach to drug development
- Validation of KemPharm's business strategy and corporate vision

Apadaz™ Product Overview

- IR opioid fixed-dose combination product comprised of 6.67 mg benzhydrocodone HCl (a prodrug of hydrocodone equivalent to 7.5 mg hydrocodone bitartrate) and 325 mg APAP
- Prodrug consists of hydrocodone plus benzoic acid
- Developed using a 505(b)(2) regulatory pathway
  - Bioequivalent, with no food effect
- Absent of "abuse-deterrent" claims, differentiated properties based on Apadaz development program include:
  - Reduced early systemic hydrocodone exposure and delayed hydrocodone T_{max} for IN Apadaz vs. IN Norco
  - Lowered early Drug Liking for IN Apadaz vs. IN Norco in first 2 hours post dose
  - Conversion (hydrolysis) of benzhydrocodone to hydrocodone in vitro is a difficult process
- Composition-based patent expires in 2031

Apadaz Label – Key Areas of Differentiation

Section 2 (Dosage and Administration)

APADAZ:

- Initiate treatment with APADAZ at 1 to 2 tablets every 4 to 6 hours as needed for pain. Dosage should not exceed 12 tablets in a 24-hour period

Norco:

- The usual adult dosage is 1 tablet every 4 to 6 hours as needed for pain. The total daily dosage should not exceed 6 tablets

Section 12.3 (PK)

Absorption:

- The effect of a high-fat, high-calorie meal on pharmacokinetics is similar between APADAZ and immediate-release tablet of 7.5 mg hydrocodone/325 mg acetaminophen. APADAZ can be administered without regard to food.

Metabolism:

- Benzhydrocodone is a prodrug of hydrocodone and is converted to active hydrocodone by enzymes in the intestinal tract

Apadaz Label – Key Areas of Differentiation

Section 9.2

Intranasal Clinical Abuse Potential

- Over the first 2 hours post-dosing (AUC0-0.5, AUC0-1, and AUC0-2), the cumulative hydrocodone exposure was lower following intranasal APADAZ compared to intranasal hydrocodone/acetaminophen.
- Additional secondary analyses of Drug Liking based on area under the effect curve analyses (AUE) for the first half hour, hour, and 2 hours post-dosing, demonstrated numerically small differences between intranasal APADAZ and intranasal hydrocodone/ acetaminophen.

Human Abuse Liability Trials Results

- The results of the oral and intranasal human abuse potential studies did not support a finding that APADAZ can be expected to deter abuse by the oral or nasal routes of administration.

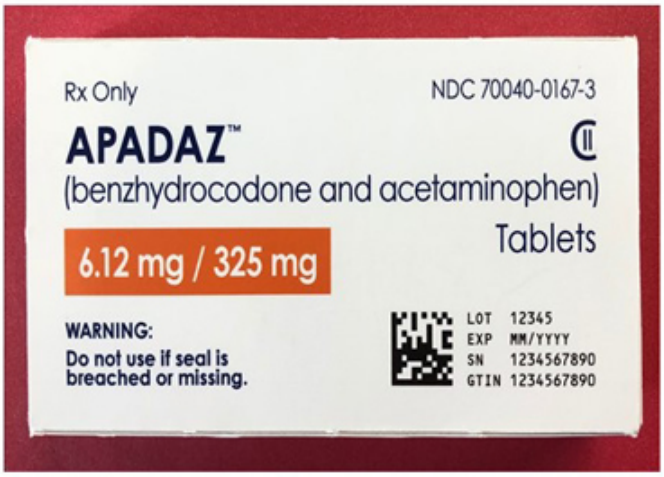
Section 9.2

In Vitro Testing

- The efficiency of extracting benzhydrocodone from APADAZ was similar compared to the efficiency of extracting hydrocodone from the non-abuse-deterrent hydrocodone/ acetaminophen control. Further conversion (hydrolysis) of benzhydrocodone to hydrocodone in vitro is a difficult process.

Apadaz Label -- Key Areas of Differentiation

100 Count Bottle	Blister Pac



Apadaz Commercialization Strategy

KemPharm is pursuing two potential strategies for commercializing Apadaz, neither strategy requires KemPharm to establish its own sales force.

Non-traditional PBM Partnerships	Pharma Partnership
• Collaborative partnerships with leading US PBMs who would agree to Tier 1 or equivalent status for Apadaz (including most favorable co-pay) in return for price parity with available generic products	• Partnership with a US-based or global generic pharmaceutical manufacturer and distributor
• PBMs would work to educate prescribers/plan sponsors and actively manage Apadaz prescriptions	• Takes advantage of generic pharma's economies of scale to optimize Apadaz COGS
	• Generic pharma partner may also utilize non-traditional PBM partnership strategy

KemPharm Expected Milestones

Product	Event	Date	
KP484	IND Filing	2017	✓
KP415	Initiate Pivotal Efficacy Study	2017	✓
Apadaz	FDA Approval	02/23/18	✓
KP415 / KP484	IV Human Abuse Liability (HAL) Data	2018	
KP415	Pivotal Efficacy Study Results	2018	
KP484	Initiate Pivotal Efficacy Study	2018	
KP415 / KP484	Oral and IN HAL Data	2018	
KP415	NDA Submission	2019	
KP484	Pivotal Efficacy Study Results	2019	
KP484	NDA Submission	2019	

KemPharm

Apadaz™ FDA Approval

February 23, 2018